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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

CASE NO. 3:18-cv-3018-JCS

ALLERGAN DEFENDANTS' NOTICE OF MOTION, MOTION TO DISMISS RELATOR'S FIRST AMENDED COMPLAINT, AND MEMORANDUM IN SUPPORT THEREOF

Action Filed: April 25, 2018

Hearing:

Date: September 20, 2019
Time: 9:30 a.m.
Courtroom: G
Judge: Chief Magistrate Judge Spero

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT on September 20, 2019, at 9:00 a.m., or as soon thereafter as the matter may be heard before the Honorable Joseph C. Spero, in Courtroom G, 15th Floor, of the United States District Court for the Northern District of California in the San Francisco Courthouse, 450 Golden Gate Avenue, San Francisco, California, 94102, Defendants Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. (collectively, the "Allergan Defendants")[1] will and do move this Court, pursuant to Rules 8(a), 12(b)(1), 12(b)(6), and 9(b) of the Federal Rules of Civil Procedure, for an order dismissing Relator's First Amended Complaint in its entirety on the grounds that Relator has failed to state a claim against the Allergan Defendants upon which relief may be granted, that he has failed to state with particularity the circumstances constituting fraud or mistake, and that the Court lacks jurisdiction over the state law claims.

The Allergan Defendants' Motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the concurrently filed Request for Judicial Notice, the concurrently filed Declaration of Emma Strong, any other matters of which the Court may take judicial notice, other documents on file in this action, and any oral argument of counsel.

ISSUES TO BE DECIDED

1. Whether the allegations and transactions underlying Relator's First Amended Complaint have been publicly disclosed (thereby barring his claims under the federal False Claims Act and state false claims statutes), and, if so, whether Relator's synthesis of material from the public domain qualifies him as an original source so as to exempt him from the public disclosure bar.
2. Whether, under Federal Rule of Civil Procedure 9(b), the First Amended Complaint adequately pleads that the Allergan Defendants violated the False Claims Act or state law analogues.
3. Whether the First Amended Complaint states a claim under the federal False Claims Act or state law analogues pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6).

[1] For purposes of this motion, the "Allergan Defendants" do not at this time include Defendant Allergan plc. In accordance with the parties' stipulation and this Court's order, Allergan plc will respond to Relator's First Amended Complaint by June 21, 2019. *See* ECF 61, 62.

4. Whether certain state law claims in the First Amended Complaint should be dismissed for lack of jurisdiction.

MEMORANDUM OF POINTS AND AUTHORITIES

Zachary Silbersher, a practicing patent attorney turned profiteering *qui tam* relator, seeks a bounty under the federal False Claims Act ("FCA") and state analogues based on fraud theories scrapped together from public information. But his claims cannot clear the first hurdle because the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4), and similar state provisions block "parasitic" outsiders from pursuing theories of fraud based on information hiding in plain sight, *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 577 (9th Cir. 2016), even where those outsiders employ some expertise to aggregate public information into purported claims, *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000).

Even if Relator could overcome this initial bar, his First Amended Complaint ("Complaint") fails to state any viable cause of action against Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, or Forest Laboratories Holdings, Ltd. (collectively, the "Allergan Defendants"). Throughout the Complaint, he relies on impermissible group pleading to sweep the Allergan Defendants into alleged misconduct by others in their dealings with the U.S. Patent and Trademark Office ("USPTO"). Relator's only actual allegation about any entity linked to Allergan—that, in connection with the so-called '009 patent, Forest Laboratories, LLC ("Forest Labs")[2] did not *remind* the USPTO of information it previously submitted to the USPTO—does not form the basis of a fraud claim as a matter of blackletter law. More fundamentally, Relator's grand unified theory of antitrust, patent, and FCA liability hinges on a convoluted and ultimately untenable string of legal assertions and inferences.

According to Relator, Adamas Pharma LLC and Adamas Pharmaceuticals, Inc. (the "Adamas Defendants") and Forest Labs made false or incomplete submissions to the USPTO to obtain a series of patents related to two Alzheimer's drugs—Namenda XR® and Namzaric®. Relator deduces this purported fraud from various patent prosecution documents in the public record. He then posits that through these allegedly improper patents, undifferentiated "Defendants" were able to block generic competitors and charge all purchasers "monopoly" prices for the drugs. According to Relator, because

[2] Forest Labs, as pleaded by Relator and used in this brief, is *not* Forest Laboratories Holdings, Ltd., but rather a separate corporate entity.

the market prices for the drugs were artificially inflated, all government purchases of, and reimbursements for, these drugs were necessarily the result of "false claims."

As a fundamental feature of our patent system, Congress has provided that pharmaceutical companies may obtain patent protection for their products and may prevent generic competition during the period of patent validity. This system rewards innovation, ensures robust investment in the development of new and innovative drugs, and enhances public health.[3] Congress also prescribed vehicles to challenge the validity of patents—both at the USPTO and in the courts. The FCA is not one of them. To the Allergan Defendants' knowledge, no plaintiff has convinced a court to police pharmaceutical patents using the FCA. It is no surprise then that the United States and the other Plaintiff governments,[4] whose claims Relator asserts in this *qui tam* action, decided not to join this suit.

In sum, this Court should reject Relator's effort to bootstrap a patent claim into an FCA case and dismiss the Complaint with prejudice for multiple, independent reasons:

First, the FCA's "public disclosure" bar, 31 U.S.C. § 3730(e)(4), requires dismissal. The FCA and the analogous state statutes allow relators to take a significant share (up to a third) of the government's recovery when they successfully prosecute fraud on the government's behalf. But these laws expressly avoid creating an open season for bounty hunters. Instead, relators (typically whistleblowing insiders) must bring forth "independent" and "material[]" new information that is not "substantially the same" as allegations or transactions already in the public record. *Id.* Here, Relator's claims cannot satisfy this standard because his "fraud on the USPTO" theory repackages patent materials that have been public for years. Similarly, he lifts from the public record each key factual allegation about proceedings before the U.S. Food and Drug Administration ("FDA") and in the courts,

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[3] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in Titles 15, 21, 28, and 35 of the U.S. Code) (commonly known as the Hatch–Waxman Act); *see also* 130 Cong. Rec. 23764 (Aug. 10, 1984) (statement of Sen. Hatch) (describing need to create "incentive[s] for innovation," ensure "commitment to research and development," and thereby enhance the "number of new drugs" available to contribute towards the "length and quality of life").

[4] The Plaintiff governments are: the United States; California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; and the District of Columbia.

as well as about government purchases of (or reimbursements for) the products at issue. Because Relator is an outsider with no new material information to contribute, he cannot be an "original source" under the FCA (or the state analogues), and his Complaint cannot survive.

Second, Relator's allegations about the '009 patent fail as a matter of law because he does not plead a cognizable theory of fraud on the USPTO. Relator's only allegation regarding the '009 patent is that Forest Labs failed to *remind* the USPTO of prior art that Forest Labs itself previously submitted. *See* Compl. ¶ 96. As a matter of blackletter law, however, refreshing the USPTO's recollection is not required, so Relator's assertions cannot support an inequitable conduct theory, much less his fraud claims. *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000).

Third, Relator's allegations about the remaining patents (the so-called "Went patents") fail as to the Allergan Defendants for the simple reason that they do not allege that *the Allergan Defendants* committed any misconduct whatsoever. Based on the timeline set forth in Relator's Complaint, any supposed fraud on the USPTO would necessarily have occurred before any Allergan Defendant ever entered into a licensing agreement with the Adamas Defendants. Relator nowhere alleges that any Allergan Defendant participated in, or knew about, the alleged misconduct, and therefore he has not stated a claim against the Allergan Defendants based on the Went patents.

Fourth, in addition to these other dispositive deficiencies, Relator's Complaint fails to plead a false claim or a false statement material to a false claim. Although he litters his Complaint with assertions about unspecified "false claim[s]" and "express and implied assurances," *e.g.*, Compl. ¶ 6, Relator never plausibly pleads that any Allergan Defendant submitted a false claim or made a statement regarding the patents or its pricing in connection with a claim for reimbursement. Relator's failure to identify any actual false claim or statement is fatal to a case brought under the FCA.

Fifth, even assuming that Relator could allege a false claim or misrepresentation, he does not adequately plead that the alleged assertions would have been material to the government's decision to pay for the drugs at issue. The Complaint's conclusory statement that the allegations are material to payment is not supported by any well-pleaded facts. Patents are invalidated all the time in the ordinary push-and-pull of the patent system. Resolution of complex patent validity and enforceability issues is simply part of the carefully designed statutory system, and Relator nowhere contends that any

government health care program would (or ever has) changed its reimbursement policies for drugs based on patent disputes.

This Complaint should give the Court serious pause. Relator asks this Court to bless a theory that could turn *every single* pharmaceutical patent that is invalidated or found unenforceable into the predicate for an FCA claim, based on nothing more than a *post hoc* recasting of materials in the patent applications as "fraud" on the USPTO. Until Relator's slew of suits, there were (to the Allergan Defendants' knowledge) just two cases claiming that defendants violated the FCA by foreclosing generic drugs—*Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA*, 856 F.3d 696, 705 (9th Cir. 2017), and *United States ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A (E.D. Va. Sept. 29, 2004). Neither case survived scrutiny under Rule 12. The same result is warranted here.

FACTUAL BACKGROUND

Relator is a New York patent attorney who has recently filed several suits under the FCA against pharmaceutical companies that have had patents invalidated or found unenforceable, relying on the same statutorily foreclosed strategy. *See* Compl., *United States ex rel. Silbersher v. Valeant Pharm. Int'l Inc.*, No. 3:18-cv-1496-JD (N.D. Cal. Mar. 8, 2018); Compl., *United States ex rel. Silbersher v. Janssen Biotech, Inc.*, No. 3:17-cv-7250-JST (N.D. Cal. Dec. 21, 2017).

Procedural Posture. Relator filed this case under seal, as required under the FCA and state analogues, to provide the Plaintiff governments an opportunity to evaluate his claims. The federal government declined to intervene. ECF 7. Relator then filed the present amended complaint, ECF 12, and shortly thereafter, each Plaintiff state also declined to intervene, ECF 15. The case was then unsealed. ECF 20.

Pharmaceuticals and Patents. The two drugs at issue here are treatments for individuals with dementia and Alzheimer's disease. The FDA initially approved Namenda® in 2003; the version of the drug at issue in this case, Namenda XR®, is an extended release version of the drug approved by the FDA in June 2010. Compl. ¶¶ 50–51. Namzaric®, which pairs the active ingredient in Namenda XR® with that in another Alzheimer's drug, was initially approved by the FDA in 2014. *See id.* ¶ 108.

Relator's Allegations. The Complaint's two core allegations[5] relate to patents obtained in 2011 and 2012, when the Adamas Defendants and Forest Labs, respectively, sought patents for new formulations and delivery methods for Namenda®.

- ***Went Patents.*** Relator alleges that Dr. Greg Went, the CEO and founder of Adamas, misrepresented the scientific findings of studies that the Adamas Defendants used to support applications for a series of related patents. Compl. ¶¶ 58–88. Specifically, Relator asserts that Dr. Went submitted declarations that downplayed the side effects associated with the extended release version of the active ingredients in Namenda®, *e.g.*, *id.* ¶ 65, and even though Went later submitted corrected declarations, *id.* ¶¶ 77, 80, the corrections allegedly only resolved *some* of the purported misrepresentations, *id.* ¶ 81.
- ***'009 Patent.*** Relator also alleges that, in connection with a separate patent, Forest Labs failed to draw the USPTO's attention to "prior art" (here a patent with an earlier invention date) that allegedly would have foreclosed the '009 patent on obviousness grounds. *Id.* ¶ 94. Relator concedes that Forest Labs submitted this prior art at "an earlier phase of the prosecution" for the same patent. *Id.* ¶¶ 96–97. But he faults Forest Labs for not doing so a second time. *Id.* ¶ 99.

Relator contends that Defendants used these patents to prevent generic manufacturers from entering the market, Compl. ¶¶ 104–09, thereby protecting the two products from competition and causing higher prices that Defendants allegedly charged to the government, *id.* ¶ 110, because prescriptions otherwise "would have been" filled by a generic, *id.* ¶ 7. According to Relator, this meant that, among other things, the products' federal list price was not "fair and reasonable," even though Defendants "would have" been required to state or certify that it was, *id.* ¶ 112, and therefore Defendants allegedly made or caused to be made claims for drug reimbursement that were knowingly false, *id.* ¶¶ 112–17.

The Various Defendants' Alleged Roles. Although Relator's pleading persistently groups various entities together as "Defendants," he acknowledges that different Defendants had distinct roles in the purported fraud set forth in the Complaint. Relator asserts that the Adamas Defendants applied for and obtained the Went patents relying on declarations that allegedly defrauded the USPTO. *See* Compl. ¶¶ 58–90. He contends that Forest Labs licensed the Went patents starting in 2012, *id.* ¶ 58,

[5] For reasons that are unclear, Relator also refers to a '703 patent in multiple places, but concedes that that patent "has not blocked generic entry." Compl. ¶¶ 4, 103. He neither alleges fraud on the USPTO in connection with the '703 patent, nor asserts that the patent was ever used to block generic entry. The Court should therefore disregard these allegations.

after the conduct at issue. But he does not allege that any Allergan Defendant participated in, knew about, or was otherwise involved in the conduct related to the Went patents (despite referring generally to "Defendants" when discussing the conduct related to the Went patents). On the other hand, Relator contends that Forest Labs was responsible for the conduct related to the '009 patent. *Id.* ¶ 91.

LEGAL STANDARD

Applicable Pleading Requirements. To survive scrutiny under Rules 8(a) and 12(b)(6), a plaintiff must allege facts that, if true, would "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A plaintiff cannot overcome a motion to dismiss by pointing to allegations that "permit the court to infer . . . the mere possibility of misconduct." *Id.* at 679. Nor can a plaintiff rely on "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* at 678. A complaint may be dismissed for two reasons: (i) lack of a cognizable legal theory, or (ii) insufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988).

Because the FCA and the related state false claims acts are anti-fraud statutes, relators also must satisfy Rule 9(b)'s strict pleading standard, which requires stating "with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *see Cafasso ex rel. United States v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 (9th Cir. 2011). Relators pursuing claims under the FCA must plead, at a minimum, the specific "who, what, when, where, and how" of the alleged fraud. *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (citation omitted).

At this stage, the Court "*must* consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (emphasis added).[6]

Finally, under Rule 12(b)(1), the Court must dismiss any remaining state law claims for lack of jurisdiction, either because the Relator fails to meet the jurisdictional requirements of the statutes, or

[6] Allergan is filing a Request for Judicial Notice that attaches as exhibits prior public disclosures of the transactions and allegations in the Complaint.

due to the dismissal of the only federal claim in the case. *See Wade v. Reg'l Credit Ass'n*, 87 F.3d 1098, 1101 (9th Cir. 1996) ("Where a district court dismisses a federal claim, leaving only state claims for resolution, it should decline jurisdiction over the state claims and dismiss them without prejudice.").

False Claims Act. The FCA imposes treble damages and per-claim penalties on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," as well as any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). Although amended periodically, the FCA's "focus [has] remain[ed] on those who present or directly induce the submission of false or fraudulent claims." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). To state an FCA claim, Relator must adequately plead "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006). Scienter under the FCA requires that a person act "knowingly"—i.e., with "actual knowledge," in "deliberate ignorance of the truth," or "in reckless disregard of the truth." 31 U.S.C. § 3729(b)(1). To plead materiality, Relator must plead that "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996. And because the FCA attaches liability to claims for payment, Relator must identify either "representative examples" of actual false claims or, at least, "details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ebeid*, 616 F.3d at 999.

ARGUMENT

I. Relator's Claims Are Barred Because He Is Not an Original Source of the Publicly Disclosed Allegations and Transactions Underlying His Complaint

Congress passed the FCA to incentivize relators with genuinely valuable insider information to come forward, but also sought to preclude recovery by "parasitic" plaintiffs "who have no significant information of their own to contribute." *Mateski*, 816 F.3d at 570, 577 (quoting *Graham Cty. Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294–95 (2010)). To strike that balance, Congress enacted a "public disclosure bar," which states that courts "shall" dismiss an action "if substantially the same allegations or transactions . . . were publicly disclosed" in specified sources

before the action was filed, unless the relator is an "original source of the information." 31 U.S.C. § 3730(e)(4)(A).[7]

There are two ways to qualify as an original source. Under the first, the relator must have "prior to a public disclosure . . . voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based." 31 U.S.C. § 3730(e)(4)(B)(i). Under the second, the relator must "ha[ve] knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and . . . ha[ve] voluntarily provided the information to the Government before filing" the FCA suit. *Id.* § 3730(e)(4)(B)(ii).

When the public disclosure bar is triggered and the relator is not an original source, the suit must be dismissed under Rule 12(b)(6). *See, e.g.*, *United States ex rel. Calva v. Impac Secured Assets Corp.*, No. SACV 16-1983-JVS(JCGx), 2018 WL 6016152 (C.D. Cal. June 12, 2018) (dismissing on these grounds under 2010 FCA amendments). All but one[8] of the state statutes invoked here (summarized in Appendix B) have a materially similar formulation, although some frame this threshold issue as a matter of "standing" or "jurisdiction."[9]

The public disclosure bar has a "broa[d] sweep," requiring dismissal here. *Schindler Elevator Corp., v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011) (alteration original; quotation omitted). As detailed below, Relator's claims are not only "substantially" based on previously disclosed allegations and transactions, they are *entirely* premised on public documents. Further, Relator is not an original source under either of the statutory prongs. As to the first, there is no indication Relator made any disclosure to the government before the public disclosures occurred—or that he even had the

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[7] The "substantially the same" formulation, adopted in the 2010 FCA amendments, codified the Ninth Circuit's existing case law interpreting the "based upon" formulation in the prior version of the statute. *Mateski*, 816 F.3d at 569 n.7, 573 n.14.

[8] The sole exception is one of the two New Mexico statutes, N.M. Stat. Ann. § 44-9-9(D), which provides for dismissal on these grounds only upon motion of the state's attorney general.

[9] The 2010 FCA amendments changed the federal public disclosure bar from a jurisdictional requirement to an affirmative defense. *See Prather v. AT&T, Inc.*, 847 F.3d 1097, 1102 (9th Cir. 2017). But dismissal for failure to clear the bar is still mandatory at this stage, albeit under Rule 12(b)(6) rather than Rule 12(b)(1). *United States ex rel. Kraxberger v. Kan. City Power & Light Co.*, 756 F.3d 1075, 1083 (8th Cir. 2014) ("[T]he [amended] FCA *requires* a court to dismiss a claim based on public disclosure."). Moreover, the public disclosure bar remains a jurisdictional issue under several state statutes invoked by Relator, and those claims should be dismissed under Rule 12(b)(1) for failure to adequately plead jurisdiction. *See* Ind. Code § 5-11-5.5-7(f); N.M. Stat. Ann. § 27-14-10(C); N.J. Stat. Ann. § 2A:32C-9(c); Mich. Comp. Laws § 400.610a(13).

information with which to do so at that point. 31 U.S.C. § 3730(e)(4)(B)(i). As to the second, "independent" knowledge means knowledge that *precedes* the public disclosures. *Amphastar*, 856 F.3d at 705 (affirming dismissal on this ground) (citing 31 U.S.C. § 3730(e)(4)(B)(ii)). But Relator had no such knowledge, let alone any that added "materially" to the public record on which he relies. 31 U.S.C. § 3730(e)(4)(B)(ii).

A. Relator's Claims Are Covered by the Public Disclosure Bar's "Broad Sweep"

The public disclosure bar is triggered by "substantia[l]" prior public disclosure of either the "allegations" or the "transactions" in the suit. 31 U.S.C. § 3730(e)(4)(A). This "is not mere semantics," but a reflection of two independently sufficient triggers. *Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992). An "'*allegation*' . . . refer[s] to a direct claim of fraud, and '*transaction*' . . . refer[s] to facts from which fraud can be inferred." *Mateski*, 816 F.3d at 570, 571 (citing 31 U.S.C. § 3730(e)(4)(A) (emphases added)). As the Ninth Circuit has explained: "If X + Y = Z," then "Z represents the allegation of fraud and X and Y represent its essential elements," i.e., a "misrepresented state of facts [X] and a true state of facts [Y]," "from which readers or listeners may infer Z." *Id.* If *either* side of the equation has been disclosed—"*X+Y*" (the transactions) or "*Z*" (the allegations)—the suit is barred. *Id.* The courts have "consistently held" that the disclosures "need not have been made public in a single document." *United States ex rel. Hong v. Newport Sensors, Inc.*, No. SACV 13-1164-JLS (JPRx), 2016 WL 8929246, at *6 (C.D. Cal. May 19, 2016) (quoting *United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 n.1 (9th Cir. 2006)); *see also United States ex rel. Law Project for Psychiatric Rights v. Matsutani*, No. 3:09-CV-0080-TMB, 2010 WL 11526903, at *8 n.98 (D. Alaska Sept. 24, 2010), *aff'd*, 454 F. App'x 644 (9th Cir. 2011).

1. The Transactions Alleged in the Complaint Were Publicly Disclosed

The "transaction" prong of the public disclosure bar precludes suits when "the material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain." *A-1 Ambulance*, 202 F.3d at 1243. This does not require "an explicit 'allegation' of fraud" in the prior disclosures. *Mateski*, 816 F.3d at 571 (quoting *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1473 (9th Cir. 1996)). In other words, "[t]hat the disclosed transactions themselves may not have pointed directly to any wrongdoing is simply of no moment." *A-1 Ambulance*, 202 F.3d at 1245. Accordingly, "[a]

relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *Id.* (quotation omitted).

A relator cannot avoid the public disclosure bar by applying specialized expertise to public information: "[t]he mere fact that [a relator's] own expertise in the area . . . may have enabled [him] to formulate [a] novel legal theory of fraud is *irrelevant* to the question of whether the material transactions giving rise to the alleged fraud were already disclosed in the public domain in the first place." *A-1 Ambulance*, 202 F.3d at 1245 (emphasis added). Thus, a "*qui tam* claim *cannot* proceed" if all a relator contributes is use of "his or her unique experience or training to conclude that the material elements already in the public domain constitute a false claim." *Id.* (emphasis added).

Finally, any doubt about the application of these rules must be resolved against allowing the suit to proceed. The Ninth Circuit has directed that courts should "rea[d] the 'transactions' portion of [the public disclosure bar] inclusively," consistent with what the Supreme Court has described as the bar's "'broad'" reach. *Mateski*, 816 F.3d at 565 n.9 (quoting *Schindler*, 563 U.S. at 408).

These well-established principles determine the outcome here. Every single significant fact that Relator alleges—both "*X*" and "*Y*"—has long been publicly available. This is obvious from the Complaint itself, which identifies many of the public documents on which Relator bases his claims. As to the few allegations for which Relator does not affirmatively cite his public source, there is ample evidence that the same facts were publicly available well before he filed this suit. Appendix A to this Memorandum of Points and Authorities catalogues each material allegation and its corresponding public source (or sources).

The crux of Relator's theory is that various patents were improperly obtained, allegedly with the ultimate effect of inflating drug prices. As detailed below, Relator's claims are drawn from the public patent prosecution files, which have been available for many years to anyone with an Internet connection. Indeed, the last of the prosecution files for the patents at issue here was published in June 2013, five years before this suit. *See* Strong Decl. Exs. 14–26.[10]

[10] Patent applications are "published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought." 35 U.S.C. § 122(b)(1)(A). After that point,

As to the Went patents, Relator admits that his allegations are all based on what "[t]he prosecution histories for the Went Patents . . . show." Compl. ¶ 90. He "sum[s]" up his theory as follows: Dr. Went allegedly made a "false" statement in the application and "knew this was false because in a separate, related patent application within the same family, he disclosed the actual results of the ME110 Study." *Id.* ¶ 83. Relator asserts that the asserted false statement was material to the USPTO given the difference in outcomes depending on whether the examiner had the "true" or "actual" information. *Id.*; *see also, e.g.*, *id.* ¶¶ 65–66 (quoting Original Went Declaration and reproducing table in that Declaration); *id.* ¶ 69 (comparing the Original Went Declaration to the May 7 Went Declaration (and table therein) filed in a related application); *id.* ¶ 80 (comparing Third Went Declaration to prior Went Declarations). Comparing the various declarations, Relator asserts that the public record contains both the "true" state of affairs ("*Y*") (i.e., the May 7 Declaration) and the "false" state of affairs ("*X*") (i.e., the other Went Declarations). *See* Strong Decl. Exs. 32–34, 38–42, 45–46 (public copies).

To be sure, Relator embellishes his basic theory. But he does so only with additional citations and quotations to other materials in the public Went patent prosecution histories. Almost every paragraph of this section of the Complaint (¶¶ 58–90) cites or quotes one or more documents from the public patent application files. *See, e.g.*, Compl. ¶ 62 (Strong Decl. Ex. 37, the June 21, 2010 Office Action); *id.* ¶¶ 70–71 (Strong Decl. Ex. 43, the Oct. 24, 2012 Office Action); *id.* ¶ 70 (Strong Decl. Ex. 44, the May 8, 2013 Abandonment); *id.* ¶ 71 (Strong Decl. Ex. 35, the Feb. 8, 2011 Non-Final Rejection); *id.* ¶ 72 (Strong Decl. Ex. 36, the May 11, 2011 Gilman Declaration).

As to the '009 patent, Relator asserts that Forest Labs made a particular disclosure of prior art "at an earlier phase of the prosecution," but failed to do so again later, leading to the allegedly improper issuance of the patent. Compl. ¶ 97. Again, both halves of the Relator's "evidence" are part of the published patent file history. *See id.* ¶ 96 (referring to Strong Decl. Ex. 31, the Aug. 14, 2006 Information Disclosure Statement; Ex. 30, the Oct. 7, 2009 List of References; Ex. 29, the June 16,

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the "complete record of the proceedings before the PTO," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005), is a "matter[] of public record" under 37 C.F.R. § 1.11(d) (promulgated Sept. 20, 2000), *U.S. Rubber Recycling, Inc. v. ECORE Int'l*, No. CV 09-09516 SJO (OPx), 2011 WL 13043495, at *2 (C.D. Cal. Aug. 8, 2011), *aff'd*, 503 F. App'x 951 (Fed. Cir. 2013). The material is published online on the "Public Patent Application Information Retrieval" website, known as "Public PAIR," and that record constitutes the agency's "Official file." *See generally* USPTO, Manual of Patent Examining Procedure § 1730(II)(B)(1)(b), (d).

2005 Specification; and Ex. 27, the Mar. 15, 2011 Claims); *see also* App. A (chart of public disclosures).

Everything that follows after Relator's allegations about the USPTO proceedings is also readily available in the public record, and again Relator often helpfully even cites the relevant source:

- Relator observes that there is an "economic benefit[] of blocking generic entry" for the brand name manufacturer; in support, he cites a U.S. Federal Trade Commission ("FTC") study and Allergan's own SEC filings discussing the impact of a generic on the drug at issue here. Compl. ¶¶ 47–48; *see* FTC, *Staff Study: Pay-for-Delay* (Jan. 2010) (Strong Decl. Ex. 48).
- He provides the relevant dates of various FDA actions, all publicly available in the agency's *Orange Book* and/or on its website, as well as from news coverage and SEC filings. Compl. ¶¶ 104–09; *see* Strong Decl. Exs. 49–55, 58–66 (copies of relevant documents).
- He similarly cites the *Orange Book* (Compl. ¶¶ 57–58) as evidence of Defendants' actions to defend their patents, and then strings together additional details on the regulatory and litigation process from public FDA materials, SEC filings, and news coverage. Compl. ¶¶ 107–09; *see* Strong Decl. Exs. 49–55, 58–66 (copies).
- He cites the licensing arrangement among certain of the Defendants, which was widely reported in the news and discussed in, and attached to, SEC filings. Compl. ¶ 58; *see* Strong Decl. Exs. 49–53, 66 (copies).
- He cites and quotes various public regulations, laws, and published federal procedures relating to sales of pharmaceuticals to the federal government. Compl. ¶¶ 112–16, 155.
- And finally, he relies on federal data and SEC filings for various data on Namenda® and Namzaric® drug sales to the government. Compl. ¶¶ 132–36.

This information has long been public. *See* App. A. Indeed, Relator concedes that his data with respect to drug sales (the alleged "false claims") is limited to what has been publicly reported. *See, e.g.*, Compl. ¶ 136 (noting that 2016 is "the last year for which Medicaid statistics are available"). Relator offers no "genuinely new and material information," let alone enough of it to avoid the conclusion that the lawsuit is "substantially" based on previously disclosed information. *Mateski*, 816 F.3d at 577. Even if there were no allegation of fraud in the extensive public materials (and there is), the entire premise of the "*X*+*Y*" trigger is that there does not need to be "an explicit 'allegation' of fraud." *Id.* at 571.

Two Ninth Circuit opinions confirm that Relator's Complaint must be dismissed. In *A-1 Ambulance*, private ambulance providers and county governments allegedly conspired to unlawfully shift the costs for certain ambulance services from the counties to Medicare. 202 F.3d at 1242. The counties' contracts offered "little or no subsidy" for services for uninsured indigent populations,

leading the providers to "charge artificially inflated rates to Medicare-covered patients in order to offset the losses." *Id.* This resulted in an alleged Medicare subsidy for non-Medicare-eligible patients. *Id.* The disclosure bar was triggered, however, and the suit dismissed because, as the Ninth Circuit explained, "all the material transactions . . . were publicly disclosed" in the contracts with the ambulance providers and related procurement process documents, including: how much (if any) the counties were contributing to cover services for indigent patients, the amount the providers were allowed to charge Medicare for eligible patients, and if those reimbursements would "be sufficient." *Id.* at 1244–45. As is to be expected with the "transactions" trigger, the prior disclosures were spread across multiple public sources. *See Catholic Healthcare W.*, 445 F.3d at 1151 n.1 (citing *A-1 Ambulance* as example of a case finding bar triggered by combination of materials in multiple sources).

Similarly, in *Amphastar* the Ninth Circuit held that the public disclosure of transactions barred another FCA case involving patent unenforceability leading to allegedly inflated drug prices. "The misrepresented facts presented to the government (via the USPTO) are that the [patented product] differed from the [prior art] because the half-life of the products was different, and thus [the defendant] held a valid patent." 856 F.3d at 704. The "true facts (actual state of the world)," as publicly disclosed in prior litigation, showed that the defendant "held an invalid patent, and this invalid patent allowed [it] unlawfully to charge monopoly prices to customers." *Id.* This was "enough to trigger the bar on its own." *Id.*

As in *A-1 Ambulance* and *Amphastar*, the "*X*" and "*Y*" that Relator pleads here have long been public. Alleging now that they equal "*Z*" does not salvage his Complaint.

2. The Complaint's Core Allegations Also Were Publicly Disclosed

Like the "transaction" prong ("*X*+*Y*") of the public disclosure bar, the "allegation" prong ("*Z*") precludes Relator's suit. The crux of Relator's allegation is that Defendants improperly obtained various patents, allegedly resulting (after a tenuous and lengthy chain of supposed causality) in the government paying monopoly prices for brand-name drugs instead of lower prices for generic drugs. But this is not a novel theory. In a widely publicized 2014 suit, the State of New York alleged that certain Defendants engaged in anticompetitive conduct aimed at keeping generic competitors to Namenda® from entering the market by suspending sales of an earlier version of Namenda® (Namenda®

IR) upon its launch of the new Namenda® XR. *See, e.g.*, *Allergan Drops Appeal of Order Blocking Alzheimer's Drug Switch*, Reuters, Nov. 25, 2014 (Strong Decl. Ex. 64). Further, as quoted in a *Law360* article, drug purchasers alleged (in a follow-up class action) that:

> "Defendants' exclusionary conduct has delayed, prevented and impeded the sale of generic memantine hydrochloride [Namenda®] in the U.S., and unlawfully enabled Forest to sell significantly more branded memantine hydrochloride at artificially inflated prices," the complaint said. "As a consequence, plaintiff[s] . . . have sustained substantial losses and damage . . . in the form of overcharges."

Actavis, Others Plotted To Delay Generic Namenda, Suit Says, Law360, June 9, 2015 (quoting complaint) (Strong Decl. Ex. 65). The State of New York investigation and related claims did not expressly allege fraud on the USPTO, but involved an extensive, in-depth review of conduct by the Allergan Defendants related to alleged abuse of patents for the Namenda® line of products, resulting in a narrow resolution. As a result, Relator's overlapping allegations about Defendants' alleged foreclosure of generics were not necessary to put the government "on the trail" of any alleged fraud. *See United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 744 (10th Cir. 2019) ("The operative question is whether the public disclosures were sufficient to set the government on the trail of the alleged fraud without the relator's assistance." (citations and quotations omitted)).

Further, in December 2014 a generic manufacturer, facing an infringement suit filed by some of the Defendants, initiated a proceeding before the USPTO challenging the validity of one of the Went patents (U.S. Patent No. 8,362,085) on anticipation and obviousness grounds. *See* IPR2015-00410, Paper No. 1 (USPTO Dec. 18, 2014), https://ptab.uspto.gov/#/login (Strong Decl. Ex. 47).

Taken together, these are public allegations that the Allergan Defendants misused the patents to foreclose generic competition, and that the result was higher drug prices for the products at issue. As the Ninth Circuit has made clear, it does not matter whether there were specific allegations that the *government* overpaid for the drugs, because that "is an obvious inference based on the publicly disclosed allegations." *Amphastar*, 856 F.3d at 704. In light of these public reports, the "allegations" prong of the public disclosure bar independently blocks Relator's claims.

B. Each Disclosure Occurred in a Public Source Recognized by the FCA

The disclosures described above predate this 2018 suit, and each was made in one or more of the channels identified in the FCA as a source triggering the public disclosure bar: "(i) in a Federal

criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A).

Government Reports. "Reports" in the FCA encompasses the "broad ordinary meaning" of the word, including an "official or formal statement of facts or proceedings." *Schindler*, 563 U.S. at 408 (quotation omitted). By law, the USPTO prosecution histories are published as an official, formal statement of federal proceedings. *See* 37 C.F.R. § 1.211 (promulgated Sept. 20, 2000); *supra* n.10 (describing public nature of prosecution file). That holds true for the USPTO-originated materials cited by Relator, such as the patent examiner's actions, as well as the information submitted by the applicants. Multiple courts have concluded that comparable materials are public "reports" for purposes of the FCA, including medical device summaries submitted by manufacturers to the FDA, and then released by the agency as part of its regulatory process; customs data that the Department of Homeland Security requires from shippers and then disseminates to the public; and drug product utilization data submitted by manufacturers and states, and then released by the Centers for Medicare and Medicaid Services.[11]

The SEC filings and FDA materials on which Relator relies are also public disclosures. The courts recognize that SEC filings so qualify (in reasoning that also applies to the patent filings) because they are "mandatory" filings made at the "request of" and "made public by the SEC in the course of carrying out its activities as a federal agency." *United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 257 (4th Cir. 2012); *see also United States ex rel. Carter v. Bridgepoint Educ., Inc.*, No. 10-CV-1401 JLS (WVG), 2015 WL 4892259, at *6 (S.D. Cal. Aug. 17, 2015) (citing *Jones*); *Newport Sensors*, 2016 WL 8929246, at *6. And the FDA *Orange Book*, in both print and online versions, together with other parts of the "Drugs@FDA" website also qualify as a "report" under the

[11] *See United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 518 (N.D. Tex. 2012) ("[T]he important factor is that it is released by the FDA as part of its administrative clearance process for medical devices."), *aff'd*, 858 F.3d 365 (5th Cir. 2017); *United States ex rel. Doe v. Staples, Inc.*, 932 F. Supp. 2d 34, 40 (D.D.C. 2013) (explaining that, by law, DHS was "requir[ed] . . . to provide vessel manifest information to the press"), *aff'd*, 773 F.3d 83 (D.C. Cir. 2014); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 2014 WL 4375638, at *10 (E.D. Pa. Sept. 4, 2014) (same as to customs data); *United States ex rel. Conrad v. Abbott Labs., Inc.*, No. 02–11738, 2013 WL 682740, at *5 (D. Mass. Feb. 25, 2013) (the drug "data files represent at least some minimal preparation and synthesis by the agency").

FCA: they are a meticulously curated and regularly updated reporting of vast troves of information about prescription drug approvals and related patent issues. *See* Drug Approvals and Databases, FDA, https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases; *United States ex rel. Ambrosecchia v. Paddock Labs., LLC*, No. 4:12-cv-2164 RLW, 2015 WL 5605281, at *6 (E.D. Mo. Sept. 23, 2015) (holding that *Orange Book* qualifies as public disclosure), *aff'd*, 855 F.3d 949 (8th Cir. 2017); *Abbott Labs., Inc.*, 2013 WL 682740, at *4 (same); *see also United States ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, 739 F. Supp. 2d 396, 405, 407 (S.D.N.Y. 2010) (holding that a "database available on a government website" can qualify as a "report" under the public disclosure bar when "readily available," "free," and "easily navigable").[12]

News Media. To the extent they did not occur in federal "reports," the disclosures here occurred in "news media" as the term is used in 31 U.S.C. § 3730(e)(4)(A)(iii). Courts repeatedly have held that information available to the public on the Internet (particularly from government and journalistic sources that exist for the purpose of disseminating information) so qualifies. *See, e.g.*, *Newport Sensors*, 2016 WL 8929246, at *5 (citing cases and holding that "[i]nformation publicly available on the Internet generally qualifies as 'news media'"); *see also United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (agreeing with string of cases holding that "publicly available websites, which are intended to disseminate information . . . qualify as news media for purposes of the public disclosure provision"). As noted above, the USPTO prosecution histories, FDA materials, and SEC filings are all available online—on websites expressly designed for the purpose of disclosing them. Thus, they too qualify as "news media."[13] In any event, these same materials also

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[12] The 2010 amendments to the FCA narrowed the list of enumerated channels in some respects, but Congress also expanded the pertinent category of "reports." "Administrative" reports was changed to the current broader formulation of "other" federal reports, reinforcing the conclusion that the FDA, SEC, and patent materials qualify as public disclosures. *Compare* 31 U.S.C. § 3730(e)(4) (1986), *with* 31 U.S.C. § 3730(e)(4) (2018).

[13] *See also, e.g.*, *Bridgeport Educ.*, 2015 WL 4892259, at *6 n.4 ("[T]he Court finds that the online comment . . . qualifies as a public disclosure as news media" because it occurred on a "a well-established website designed to convey the news to the public"); *United States ex rel. Green v. Serv. Contract Educ. & Training Tr. Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012) ("[C]ourts that have considered the issue have construed the term to include readily accessible websites."); *United States ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413, 2007 WL 4557788, at *14 (N.D. Cal. Dec. 21, 2007) ("The 'fact' of the contracts . . . was publicly disclosed in the news media, as that information was available on the Internet.").

qualify as news media because they are available through various commercial services, often in databases with enhanced functionality and features. *See, e.g.*, Make Better Decisions, DrugPatentWatch, https://www.drugpatentwatch.com/; LexisNexis, https://www.lexisnexis.com/en-us/products/lexis-securities-mosaic/sec-database-and-intuitive-edgar-research.page. *Cf. Staples*, 932 F. Supp. 2d at 40 ("[N]ews media" includes "reports published by . . . a company which compiles manifest information submitted to Customs by all shippers." (quotation omitted)); *Victaulic Co.*, 2014 WL 4375638, at *10 (same).

C. Relator Is Not an Original Source

Because Relator's suit is premised on "substantially the same allegations or transactions" as those that were previously disclosed, the Court must dismiss the Complaint unless Relator is an original source. 31 U.S.C. § 3730(e)(4)(A). Qualifying as such a source is especially challenging for outsiders like Relator, who are unlikely to have the nonpublic, insider information necessary to satisfy the statute's requirements.

This Relator plainly is not an original source. He does not even allege any facts showing that he voluntarily provided the government the "information on which allegations or transactions in [the] claim are based" before any public disclosure was made. 31 U.S.C. § 3730(e)(4)(B)(ii). Indeed, he had no such information he could have disclosed at that time, because his information came *from* the public patent files. *See supra* Section I.A.1 (discussing Compl. ¶¶ 58–90). Nor did he have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B)(ii).[14]

To be sure, Relator does make a few conclusory statements to the effect that he is an original source. *See* Compl. ¶¶ 10, 22. But a complaint that "simply parrots the standard for determining an original source without providing any factual basis for the claim" fails to defeat the public disclosure bar. *United States v. Kimberly-Clark Corp.*, No. LA CV-14-08313 JAK (JPRx), 2017 WL 10439690, at *8 (C.D. Cal. Nov. 30, 2017). A close examination of the Complaint reveals this is not a pleading

[14] In the event that the Court concludes Relator did have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," Allergan reserves any argument that Relator did not comply with his obligations to make a pre-suit disclosure to the federal and state governments of that information. *See* 31 U.S.C. § 3730(e)(4)(B)(ii).

deficiency that could potentially be overcome with an amendment, but rather a fundamental problem with the premise of the suit.

First, because Relator's knowledge is derived from piecing together public disclosures, he cannot have known of his claims before the public disclosures occurred—leaving him ineligible under either variant of the original source exception. Under the first, a relator necessarily must have preexisting knowledge in order to provide it to the government before the public disclosure. 31 U.S.C. § 3730(e)(4)(B)(i). This relator had no such knowledge. Nor can he meet the second test. Although the 2010 FCA amendments removed the requirement for "direct" knowledge, the FCA still requires "independent" knowledge, and Relator has none. *See* 31 U.S.C. § 3730(e)(4)(B)(ii). "To prove 'independent knowledge' relators *have to show* they had relevant evidence of fraud *prior to the public disclosure*." *Amphastar*, 856 F.3d at 705 (quotation omitted; emphases added); *Malhotra v. Steinberg*, 770 F.3d 853, 860 (9th Cir. 2014) (requiring relators "to show that they knew of the information underlying the kickback scheme allegations before" the public disclosure). Again, Relator cannot satisfy this requirement.

Second, a relator cannot be an original source by applying specialized knowledge of legal and patent issues to publicly disclosed "transactions"; "simply conducting a specialized analysis of publicly available information based on his expertise does not make him an 'original source.'" *Calva*, 2018 WL 6016152, at *8. Nor does "[a] relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction . . . alter the fact that the material elements of the violation already have been publicly disclosed." *Prather*, 847 F.3d at 1105. In short, "[i]f a relator merely uses his or her unique experience or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed." *A-1 Ambulance*, 202 F.3d at 1245; *see also United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020–21 (9th Cir. 1999) (affirming district court's conclusion that relator was not an original source under the FCA "because his investigation merely added a legal name to describe the alleged circle of facts"). Similarly, it is insufficient to "provide only background information and details relating to the alleged fraud" beyond what has already been disclosed. *United States ex rel. Hastings v. Wells Fargo Bank, NA, Inc.*, 656

F. App'x 328, 331–32 (9th Cir. 2016). That is all Relator has purported to do, even though the FCA demands much more.

* * *

Under Congress's carefully crafted provisions, an FCA suit must be dismissed when "substantially the same allegations or transactions . . . alleged . . . were publicly disclosed" before the action, with a sole exception for a relator who is an "original source of the information." 31 U.S.C. § 3730(e)(4). This is the prototypical "parasitic" lawsuit that the public disclosure bar is designed to prevent: it is based entirely on long-public information and brought by a plaintiff who has "no significant information of [his] own to contribute." *Mateski*, 816 F.3d at 570, 577 (quoting *Graham Cty. Soil*, 559 U.S. at 294–95). This Court should dismiss the Complaint with prejudice.

II. Relator's Allegations Regarding the '009 Patent Must Be Dismissed Because They Do Not Plausibly Allege Fraud on the USPTO

Relator asserts that Forest Labs obtained the '009 patent "through fraud." Compl. ¶¶ 91–102. Specifically, Relator posits that Forest Labs disclosed a prior art reference to the USPTO during its prosecution of the '009 patent, but did not re-flag the reference for the examiner after amending its claims. *Id.* ¶¶ 94, 96. This theory fails as a matter of law and logic.

It is blackletter law that there can be no inequitable conduct (i.e., fraud on the USPTO) by withholding a reference to prior art where the reference was disclosed elsewhere to the USPTO. *See, e.g.*, 37 C.F.R. § 1.56(a) (promulgated Jan. 17, 1992) ("The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office . . . ."). As stated by the Federal Circuit, "[a]n applicant is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for inequitable conduct." *Fiskars*, 221 F.3d at 1327; *id.* ("Fiskars' citation as prior art defeats Hunt's charge that the Maruzen device was withheld with deceptive intent."). This principle is entirely logical: "[w]hen a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it cannot be deemed to have been withheld from the examiner." *Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1185 (Fed. Cir. 1995) (concluding it was "clearly erroneous" to invalidate a patent where prior art was previously cited (citation omitted));

see also Pixion, Inc. v. Citrix Sys., Inc., No. C 09-03496-SI, 2012 WL 1309170, at *3–4 (N.D. Cal. Apr. 16, 2012) (rejecting claims of inequitable conduct where prior art was not referenced in an Information Disclosure Statement, but was "disclosed . . . in [plaintiff's] prosecution of the child patents [of the parent patents at issue]"). Thus, Relator's legal theory fails as a matter of law.

Further, Relator does not plausibly allege that Forest Labs *knowingly* concealed the prior art. *See* 31 U.S.C. § 3729(a)(1) (imposing liability only for "knowing" conduct); *cf. Therasense, Inc. v. Becton, Dickinson & Co*., 649 F.3d 1276, 1290 (Fed. Cir. 2011) ("To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO." (citations omitted)). At best, Relator *speculates* that Forest Labs deliberately decided not to disclose prior art during resubmission, pleading such on "information and belief." Compl. ¶ 97. But "[c]laims made on information and belief are not usually sufficiently particular [under Rule 9(b)], unless they accompany a statement of facts on which the belief is founded." *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1042 (9th Cir. 2010). Here, Relator supplies no facts whatsoever to support his speculation, just a conclusory allegation that is at odds with the law. He thus fails to satisfy Rules 9(b) or 12(b)(6).[15] *See Twombly*, 550 U.S. at 570 (holding that a complaint fails where plaintiffs "have not nudged their claims across the line from conceivable to plausible").

In any event, under apposite FCA case law, Forest Labs could not have acted "knowingly" to commit a fraud because it acted in an objectively reasonable manner that was consistent with a reasonable interpretation of 37 C.F.R. § 1.56(a). Where statutory or regulatory requirements are susceptible of more than one interpretation, a party does not act in reckless disregard of a statute where its reading was "not objectively unreasonable," so long as "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69, 70 n.20 (2007) (explaining the meaning of "knowing" conduct under the Fair Credit Reporting Act); *see also United States ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551, 552

[15] Moreover, "a disputed legal issue" is insufficient to support even "a reasonable inference" that a claim was false within the meaning of the FCA. *Hagood*, 81 F.3d at 1477. Rather, Relator must plausibly allege that Forest Labs made claims that were actually false—a standard he does not, and cannot, meet here. *See, e.g.*, *United States ex rel. Haight v. Catholic Healthcare W.*, No. CV-01-2253-PHX-FJM, 2007 WL 2330790, at *6 (D. Ariz. Aug. 14, 2007) (rejecting liability where statements were not "objectively false").

(9th Cir. 2017) (affirming the dismissal of FCA claims under *Safeco* because defendants' interpretation of the law was "reasonable"); *United States ex rel. Donegan v. Anesthesia Assn's. of Kan. City*, 833 F.3d 874, 879 (8th Cir. 2016) (applying *Safeco* and holding that a reasonable interpretation of the law "belies the scienter necessary to establish a[n] [FCA] claim").

Here, Forest Labs' duty to disclose was "satisfied" if all information known to be material to patentability "was cited by . . . or submitted to" the USPTO. 37 C.F.R. § 1.56(a). That information only was material to the extent it was "not cumulative to information already of record." *Id*. It is—at a minimum—reasonable to interpret that provision to mean that information previously submitted to the USPTO need not be re-flagged during resubmission of the same application. And the Federal Circuit has held just that. *See, e.g.*, *Fiskars*, 221 F.3d at 1327.[16] Because there was no "objectively unreasonable" conduct, Relator cannot plead scienter under the FCA.

Finally, it is notable that Relator's allegation only relates to conduct by Forest Labs. Relator makes no allegations against any of the other defendants with regard to the '009 patent, and they therefore cannot be liable for any alleged knowing misconduct. *See, e.g.*, *Swartz v. KPMG LLP*, 476 F.3d 756, 765 (9th Cir. 2007) ("In the context of a fraud suit involving multiple defendants, a plaintiff must, at a minimum, 'identif[y] the role of [each] defendant[] in the alleged fraudulent scheme.'" (citation omitted)).

Once Relator's theory about fraud on the USPTO by Forest Labs in connection with the '009 patent crumbles, his entire case against the Allergan Defendants collapses. Without that thin, legally invalid nexus to the Allergan Defendants, Relator has nothing more, as described below.

III. Relator's Allegations About the Went Patents Must Be Dismissed Because Relator Does Not Plead Any Conduct by the Allergan Defendants

Relator's second set of allegations—about the so-called "Went" patents—fails as to the Allergan Defendants for the simple reason that Relator does not plead *any* conduct whatsoever by the

[16] Furthermore, were the omission upon which Relator relies the result of a mistake rather than interpretation, the outcome would remain the same. "Innocent mistakes, mere negligent misrepresentations and differences in interpretations are not false certifications under the [False Claims] Act." *Gonzalez v. Planned Parenthood of L.A.*, 759 F.3d 1112, 1115 (9th Cir. 2014) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996)).

Allergan Defendants. Nor could he, because the Allergan Defendants were not involved with prosecution of those patents, as Relator's Complaint confirms.

A. Relator Does Not Plead Any Conduct by the Allergan Defendants with Regard to the Went Patents

Rule 9(b) does not allow a complaint "to merely lump multiple defendants together," but instead requires a plaintiff in a fraud suit involving multiple defendants to, "at a minimum," identify the role of each defendant in the alleged fraudulent scheme. *Swartz*, 476 F.3d at 764–65; *see also United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1184 (9th Cir. 2016) ("Rule 9(b) . . . requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." (quotation omitted)); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) (explaining that a plaintiff also must plead the "circumstances constituting" an inequitable patent conduct claim with particularity under Rule 9(b)).

With regard to the Went patents, however, Relator never articulates his theory of who, how, or when *any* of the Allergan Defendants—let alone any specific Allergan entity—participated in any alleged inequitable conduct before the USPTO. Instead, Relator resorts to the artifice of group pleading, in an apparent effort to avoid the fact that the Allergan Defendants had *nothing* to do with the alleged conduct relating to the Went patent prosecutions.

Starting at paragraph 58 of the Complaint, Relator describes the alleged fraud that underlies his entire theory as to the Went patents. Upon inspection, none of these allegations involved an actual Allergan Defendant (because they cannot). A straightforward timeline shows that no Allergan Defendant was involved with the Went patents until after all of the alleged misconduct.

Date	Allegation	Compl.
April 2006	The "parent patent" to all Went patents "was filed."	¶ 61
July 2009	Dr. Went, CEO of Adamas, and "co-inventors"—which do not include any Allergan Defendants[17]—filed a patent application.	¶ 74

[17] The "co-inventors" and "applicants" for the patents do not include any Allergan Defendants, a point that is confirmed by the publicly disclosed patent files that Relator cites in his Complaint and that are attached hereto as Exhibits 1–48 of the Strong Declaration.

April 2010	Dr. Went and "co-inventors"—which again do not include any Allergan Defendants—filed two additional patent applications.	¶¶ 75, 76
November 2010	Dr. Went submitted the "Original Went Declaration," which was allegedly fraudulent.	¶ 63
May 2011	The patent "applicants"—which do not include any Allergan Defendants—also submitted a "Gilman Declaration."	¶ 71
November 2011	The USPTO issued the "parent patent" to all of the "remaining Went Patents."	¶ 61
April 2012	On April 3, 2012, "Applicant" submitted a declaration by Dr. Went—the "Corrected Went Declaration." Dr. Went also submitted a "separate" declaration on April 24, 2012.	¶ 77
May 2012	Dr. Went submitted the "May 7 Declaration."	¶ 69
June 2012	Dr. Went also submitted a "separate" declaration on June 15, 2012.	¶ 77
June 2012	Dr. Went submitted additional information in the "Third Went Declaration."	¶ 80
November 2012	Forest Labs entered into an exclusive license with Adamas to commercialize the patents.[18]	¶ 58

This is the sequence of events for the Went patents, *as Relator pleaded it*. It establishes that no Allergan Defendant was involved in the alleged misconduct related to the Went patents.

Relator is left to rely on insufficient group pleading. Compl. ¶¶ 82–84. "A relator alleging an FCA claim must provide an adequate factual basis connecting the relator's FCA claim to the particular defendant." *United States v. Safran Grp.*, No. 15-CV-00746-LHK, 2017 WL 3670792, at *10 (N.D. Cal. Aug. 25, 2017), *aff'd sub nom. Hascoet ex rel. United States v. Morpho S.A.*, No. 17-16915, 2019 WL 2213322 (9th Cir. May 22, 2019). Generalized allegations against "Defendants" that do not "specify what role [a specific defendant]" played in the alleged fraud, and from which the Court cannot discern which entity was making false representations, require dismissal. *Hascoet*, 2019 WL 2213322, at *1.

[18] Relator pleaded that this occurred in 2012, Compl. ¶ 58, and this Court should take judicial notice of the fact that it occurred in November 2012. *See* Forest Laboratories and Adamas Pharmaceuticals Enter into Licensing Agreement for the Development and Commercialization of a Fixed Dosed Combination of Namenda XR® and Donepezil for Alzheimer's Disease, Adamas Pharmaceuticals (Nov. 13, 2012), http://ir.adamaspharma.com/news-releases/news-release-details/forest-laboratories-and-adamas-pharmaceuticals-enter-licensing; Strong Decl. Ex. 66 (copy).

Relator never articulates the "who, what, when, where, and how" of any conduct by the Allergan Defendants. Instead, he pleads facts showing the opposite—that Allergan Defendants were not involved in the fraud on the USPTO; thus, Relator has not pleaded a claim related to the Went patents against the Allergan Defendants.

B. Relator Fails to Plead That Any Allergan Defendants Acted Knowingly with Regard to the Went Patents

In addition to his obligation to plead with particularity under Rule 9(b), Relator must plead facts sufficient to show plausibly that the Allergan Defendants acted with the requisite intent—that is, with "actual knowledge," "in deliberate ignorance of the truth," or "in reckless disregard of the truth." 31 U.S.C. § 3729(b)(1). There is a very real risk of "abuse by . . . *qui tam* relators," so courts require "strict enforcement [of the scienter element]" to police against this abuse. *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010) ("*SAIC*"). As such, Relators may not "piec[e] together scraps" of knowledge of different companies, across disparate time periods. *Id.* at 1275. These types of "collective knowledge" pleadings are not permitted under the FCA. *See id.*

Here, Relator nowhere alleges that any of the Allergan Defendants, individually *or* together, had the requisite knowledge through any knowledge of the alleged underlying fraud on the USPTO at the time any subsequent claim for payment or reimbursement was made. Again, Relator alleges that the fraud on the USPTO was actually perpetrated by Dr. Went and the "Applicant"—neither of whom is, or ever had been, affiliated with any Allergan Defendant. But Relator never alleges that any Allergan Defendant even knew about the supposed fraud or learned about it after the fact. In other words, Relator offers no plausible allegations that Allergan Defendants either participated in, or knew about, the alleged fraud at any time. This omission is especially glaring when compared with allegations that Dr. Went "knew" certain of his declarations were false. *See* Compl. ¶ 83.

The closest Relator gets is pleading in entirely conclusory fashion that "Defendants were aware of a study" and "misrepresented the findings of the study to the Patent Office." Compl. ¶ 2. But as the timeline above makes clear, this conclusory group allegation cannot be squared with other allegations in the Complaint, which confirm that Forest Labs was not involved with the Went patents until *after* the alleged misrepresentations. It simply does not suffice to plead that the Adamas Defendants knew

about the fraud on the USPTO, and separately that Allergan Defendants later knew claims were being submitted to the government at prices commensurate with a patented drug. *See SAIC*, 626 F.3d at 1275.

IV. Relator Does Not Plead Any "False" Claim or Statement

"The [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment," *Cafasso,* 637 F.3d at 1055 (citations and quotations omitted), so a relator must allege a "false claim or statement" as that is "the '*sine qua non* of receipt of state funding.'" *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (citation omitted); *see* 31 U.S.C. § 3729(a)(1)(A). At the pleading stage, a relator must identify "what is false or misleading about [the claim or] statement, and why it is false." *Swoben*, 848 F.3d at 1180.

A claim or statement may be either factually or legally false. A factually false claim or statement exists when a defendant misrepresents the goods or services that it provides to the government. *Campie*, 862 F.3d at 900. Here, Relator does not allege any factually false claims or statements, because he does not allege that the goods or services paid for or reimbursed by the government—i.e., the Alzheimer's drugs—were defective or nonconforming in any way, or that they were otherwise misrepresented. Beneficiaries received what the government paid for.

A legally false claim misrepresents compliance with a law, regulation, or contractual requirement. *United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018). Under this theory, the "falsity requirement can be satisfied" either by (1) an "express false certification," which "means that the entity seeking payment [falsely] certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted," *id.*, or (2) an "implied false certification," which occurs "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement," *Escobar*, 136 S. Ct. at 1995. Relator does not meet either standard.

Relator fails to identify any actionable false claims or statements made by the Allergan Defendants. With respect to the '009 patent, the alleged failure to submit prior art to the USPTO by Forest Labs is not an actionable "false" claim or statement for purposes of the FCA. There is simply nothing "false" about truthfully submitting prior art but then not resubmitting it to the USPTO later,

and there is also no "claim" or "statement" for payment entailed in such a submission. Moreover, at least one court has expressly held that because "misrepresentations to the USPTO" years prior are "disconnect[ed]" from "invoices submitted to the government," they cannot constitute an FCA violation as a matter of law. *Hoffman-La Roche*, No. 03-1447-A (attached as Strong Decl. Ex. 67).

Relator's Complaint must therefore fall back on the theory that Defendants made "express and implied misrepresentations that [Allergan's] prices were fair and reasonable." Compl. ¶ 117. Relator contends that "Defendants" made these misrepresentations through (1) entering into a "Master Agreement" submitted to the General Services Administration ("GSA") that stated Namenda XR® and Namzaric® drug prices were "fair and reasonable," *id*. ¶ 112, and (2) submitting "product and pricing data" through the Medicaid Drug Rebate Program and "pricing data" through the Section 340B Drug Pricing Program, *id*. ¶¶ 115–16. These allegations are insufficient.

With respect to the first—that "Defendants were required to supply . . . proof that the price is fair and reasonable" to the GSA in order to be eligible for Medicare and Medicaid reimbursement, Compl. ¶ 113—this is not a certification of "compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted." *Rose*, 909 F.3d at 1017. Certifying prices as "fair and reasonable" is not an open-ended certification of compliance with every conceivable law or requirement, and certainly not an express certification of adherence to patent or antitrust laws. Rather, as documents cited by the Complaint make clear, the GSA requires proof that prices are "fair and reasonable" to ensure that the government is receiving pricing that is commensurate with (or better than) *commercial pricing*. *See* Compl. ¶ 113 (citing "About GSA Schedules," which states that "we compare the prices or discounts that a company offers the government with the best prices or discounts that the company offers to its own commercial customers"). In other words, whether a price is "fair and reasonable" is determined with regard to commercial prices, not based on an unbounded inquiry into whether the seller is in compliance with every conceivable law that could affect price. Alleging that the Allergan Defendants were "required" to certify prices as "fair and reasonable," therefore, does not satisfy the requirement of a "false" claim or statement.

Moreover, Relator alleges that Defendants were "required" to submit the "proof that the price is fair and reasonable," Compl. ¶¶ 112–16, but never alleges that the Allergan Defendants in fact did

so, let alone the "who, what, when, where, and how" of those submissions. When a Relator has "failed to identify who made false certifications of compliance with . . . U.S. antitrust laws, when such certifications were made, or the circumstances of the ostensible false certifications, . . . those claims fail[] to satisfy Rule 9(b)." *Hascoet*, 2019 WL 2213322, at *1. Relator's pleading therefore fails under Rule 9(b). *Swoben*, 848 F.3d at 1180 ("Broad allegations that include no particularized supporting detail do not suffice" under Rule 9(b).).

Relator's second theory—that Defendants submitted "product and pricing data" under various federal programs, Compl. ¶¶ 112–16—can only be read as an "implied" certification theory, since Relator does not plead the submitted prices inaccurately reflected commercial prices. Under *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), a relator must allege two conditions to state an "implied" certification claim: "first, [that] the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, [that] the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. *See also Rose*, 909 F.3d at 1017 ("[O]ur post-*Escobar* cases . . . appear to require *Escobar*'s two conditions."); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) (holding that unless a defendant "made any specific representations," relator's FCA claims fail as a matter of law).

Here, Relator does not identify any "specific representation" made by Defendants in connection with the submitted "product and pricing data" that was a "misleading half-truth." *Escobar*, 136 S. Ct. at 2001. In fact, Relator pleads almost *nothing* about the contents or substance of the product and pricing data. *See generally* Compl. Section VI.D. Defendants were not required to certify compliance with the federal patent or antitrust laws as a condition of government payment. Nor were they required to make any specific representation as to the validity of patents or the potential that those patents may be challenged through the ordinary, statutory patent process.

Tellingly, the most that Relator can allege, albeit without the support of any factual allegation or legal citation, is that "the United States Government and Plaintiff States require that the prices they pay or the amounts they reimburse have not been manipulated, inflated or maintained through the wrongful suppression of competition or other wrongful conduct." Compl. ¶ 155. This is a bald legal

conclusion, without any factual or legal allegations or citations in support. Relator does not (and cannot) identify any such requirement in either federal or state law. Without such particularized information, the Complaint does not satisfy *Escobar*'s requirement that Relator plead a "specific misrepresentation" sufficient to support an implied certification claim. Therefore, all of Relator's attempts to identify the actually "false claim" at issue fail.

V. Relator Has Not Pleaded Materiality

The Supreme Court has explained that the FCA's materiality standard is "rigorous" and "demanding." *Escobar*, 136 S. Ct. at 2002–03. The critical question is whether the alleged conduct had a "likely or actual" effect on the government's payment decision and "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996. Relator's allegations are entirely conclusory on this point; he just parrots *Escobar*'s formulation and contends that the government "would not have paid" if it knew about the alleged fraud on the USPTO, and that Defendants' conduct is "necessarily material." Compl. ¶¶ 155–56. These allegations are not supported by "facts" as required to meet the threshold requirements of Rules 9(b) and 12(b)(6). Allegations that "only point to the regulations" and alleged noncompliance therewith are "not sufficient to meet the rigorous standard for pleading materiality." *Knudsen v. Sprint Commc'ns Co.*, No. C 13-04476 CRB, 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016). Relator must plead "facts to support allegations of materiality," *Escobar*, 136 S. Ct. at 2004 n.6, which he has not done here.

Moreover, the entire patent system (as described in the Complaint) undermines Relator's contention that disputed patent applications would be material to the government's decision to pay. As alleged, Congress enacted a robust system for patent prosecutions and challenges. *See* Compl. ¶¶ 34–46. Even when patents are invalidated, the government does not seek recoupment of previously paid amounts. As the Complaint alleges, sales of Namenda XR® continued at "substantial levels in 2017 and 2018," *id.* ¶ 136, which cover the period *after* the patents were invalidated in February 2018 and generics entered the market. Indeed, the Complaint expressly alleges that the federal government "continues to pay" claims, *id.* ¶ 165, and that each state also "continues to pay," *see, e.g.*, *id.* ¶¶ 175, 187, 501. These allegations therefore belie the notion that the government's payment decision would

have changed once it knew about disputed patent issues. In other words, part of Relator's alleged theory of damages *concedes* that the government, in fact, continued to pay for these drugs after the patents were invalidated, which negates any suggestion that patent disputes would affect the government's decision to pay. *Escobar*, 136 S. Ct. at 2003.

VI. Relator's State Claims Also Must Be Dismissed

Like Relator's federal claim, his state claims also fall short of legal sufficiency, and must be dismissed. As a starting point, Rule 12(b)(1) requires dismissal because "[w]here a district court dismisses a federal claim, leaving only state claims for resolution, it should decline jurisdiction over the state claims and dismiss them without prejudice." *Wade*, 87 F.3d at 1101. Additionally, the state counts are deficient in their own right in several ways:

First, 29 of the 30 statutes invoked include a public disclosure bar based on the federal statute. Each of those bars includes "news media" as a qualifying source of a disclosure, and several of them also include federal "reports." *See* App. B (summarizing relevant provisions of state statutes). Thus the claims cannot proceed unless the Relator is an original source. On that question, too, the state provisions mimic the federal statute, either the present version (most), or the pre-2010 version (a few). *Id.* Either variant requires preexisting, "independent" knowledge. Thus, for the same reasons the Relator cannot qualify as a federal original source, he also cannot qualify as one under any of the state laws. *See supra* Section I.C; *see also, e.g.*, *United States v. Ne. Med. Servs., Inc.*, No. C 10-1904, 2014 WL 1992651, at *6 (N.D. Cal. May 13, 2014) (explaining that because the California statute "is based on the FCA, California courts typically look to FCA precedents to construe the scope of the" state law), *aff'd sub nom. La Clinica De La Raza, Inc. v. State of Cal. Dep't of Health*, 669 F. App'x 932 (9th Cir. 2016). Accordingly, these state claims must be dismissed under Rule 12(b)(6), or, in the case of several states whose bar is jurisdictional, *see* App. B, under Rule 12(b)(1).[19]

[19] A number of the states amended their statutes at some point during the course of conduct alleged here. For example, until June 21, 2018 the North Carolina statute framed its public disclosure bar in jurisdictional terms. *See* N.C. Gen. Stat. Ann. § 1-611, *amended by* 2018 N.C. Sess. Laws 2018-41, § 5. *See also* 2016 Okla. Sess. Law Serv., ch. 44, § 5, amending 63 Okla. Stat. § 5053.5(B) effective Nov. 1, 2016. For illustration, allegations about claims submitted to North Carolina prior to June 21, 2018 would be governed by the previous version of that state's statute (including its jurisdictional provision), and thus subject to dismissal for lack of jurisdiction.

Second, "it is insufficient for purposes of Rule 9(b) to merely imply state FCA claims based on alleged federal FCA claims." *United States ex rel. Chin v. CVS Pharmacy, Inc.*, No. CV 09-1293, 2017 WL 4174416, at *8 (C.D. Cal. Aug. 15, 2017). At the "very least," Relator was required to "plead facts showing how false claims were submitted to the states in violation of each state's respective statute." *Id.* But he only refers to the states' roles in the most conclusory manner, and provides no details whatsoever as to the claims supposedly submitted to *each* state, let alone how such claims allegedly violated each specific state law. This falls far short of the specific "who, what, when, where and how" of the alleged fraud required by Rule 9(b). *Ebeid*, 616 F.3d at 998.

Third, the state claims suffer from the same substantive defects as the federal claims, and should be dismissed for the same reasons. *See supra* Sections II–IV.

Fourth, certain state-specific flaws require dismissal. For example, the New Mexico statute precludes a private action absent a determination by the state of "substantial evidence that a violation has occurred," and nothing in the record indicates such a finding was made. *See United States ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015) (citing N.M. Stat. Ann. § 27-14-7(C) and dismissing on this ground).

CONCLUSION

Relator's claims are rooted in facts that were publicly disclosed, and he cannot contribute information that exempts him from the public disclosure bar imposed by both federal and state false claims statutes. Even if he could, his core allegations do not implicate the Allergan Defendants in any misconduct giving rise to an FCA claim. And even if he had adequately alleged improper activities by the Allergan Defendants, Relator's Complaint fails as a matter of law because he cannot identify any false claims or certification, and cannot satisfy the FCA's rigorous materiality standard. Each of his state law claims fails for these same reasons. Relator cannot cure these fundamental defects with further amended pleadings, and therefore the Court should dismiss the claims against Allergan Defendants with prejudice.

Dated: June 14, 2019

Respectfully submitted,

By: /s/ M. Sean Royall

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